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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/787034

INTERNATIONAL APPLICATION NO.

PCT/US97/04127

INTERNATIONAL FILING DATE

6 March 1997

PRIORITY DATE CLAIMED

TITLE OF INVENTION

Feto-Maternal Calendar Calculator

APPLICANT(S) FOR DO/EO/US

Rottem, Shraga

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

First page of the published International Application Number WO 97/33214
Copy of the International Search Report

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.53) 09/787034	INTERNATIONAL APPLICATION NO. PCT/US97/04127	ATTORNEY'S DOCKET NUMBER 43581.010100
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21. The following fees are submitted:				CALCULATIONS PTO USE ONLY	
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :					
<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO				\$1,000.00	
<input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO				\$860.00	
<input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO				\$710.00	
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)				\$690.00	
<input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4)				\$100.00	
ENTER APPROPRIATE BASIC FEE AMOUNT =				\$710.00	
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)).				<input type="checkbox"/> 20 <input type="checkbox"/> 30	\$0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	13 - 20 =	0	x \$18.00		\$0.00
Independent claims	3 - 3 =	0	x \$80.00		\$0.00
Multiple Dependent Claims (check if applicable)				<input type="checkbox"/>	\$0.00
TOTAL OF ABOVE CALCULATIONS =					\$710.00
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable).				<input type="checkbox"/>	\$0.00
SUBTOTAL =					\$710.00
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)).				<input type="checkbox"/> 20 <input type="checkbox"/> 30	\$0.00
TOTAL NATIONAL FEE =					\$710.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).				<input type="checkbox"/>	\$0.00
TOTAL FEES ENCLOSED =					\$710.00
				Amount to be refunded	\$
				charged	\$

- ☐ A check in the amount of _____ to cover the above fees is enclosed.
- ☒ Please charge my Deposit Account No. **50-1561** in the amount of **\$710.00** to cover the above fees.
A duplicate copy of this sheet is enclosed.
- ☐ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____ A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

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REGISTRATION NUMBER
8 March 2001
DATE

FETO-MATERNAL CALENDAR CALCULATOR

SHRAGA ROTTEM

This application claims the benefit of prior filed U.S. provisional application Serial No. 60/012,956, filed on March 6, 1996.

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Background of the Invention

This invention relates to a feto-maternal calendar calculator for calculating times for detection of fetal organs and fetal anomalies, as well as other prenatal tests and conditions, utilizing ultrasonogram or other diagnostic aids.

In accordance with the invention, the feto-maternal calendar calculator incorporates one or more charts with time-oriented tests, conditions, and development data, starting with 0 (zero) weeks and 0 (zero) days from the last menstrual period and ending with 40 (forty) weeks and 0 (zero) days menstrual age, and a calendar encompassing forty (40) weeks and 0 (zero) days of menstrual age.

The feto-maternal calendar calculator is preferably relatively portable.

The feto-maternal calendar calculator is preferably used to determine the length of the gestation in weeks and days from the last menstrual period, and to aid in the scheduling and interpretation of feto-maternal tests accordingly.

The calendar calculator may include times for detecting the appearance of fetal organs and structures, fetal anomalies, normal and abnormal levels of substances in the amniotic fluid, umbilical cord, and uterus, normal and abnormal levels of substances in maternal urine and serum, genetic abnormalities in the fetus, and tests on any other feto-maternal compartments, related or not related to paternal genetic information.

The calendar calculator can present an assembly of charts according to any fetal

menstrual age.

The invention is especially suitable for the following:

1. Guiding the user when to look for the ultrasonographic detection of one or more fetal organs and the development of such organs.
2. Guiding the user when to look for the ultrasonographic detection of one or more fetal anomalies.
3. Guiding the user as to the significance of the ultrasonogram and other tests. in the amniotic fluid, umbilical cord, uterus, maternal serum, urine and other fetomaternal compartments, all in relation to the menstrual age.
4. Guiding the user when to schedule fetomaternal tests.

Summary of the Invention

A fetomaternal calendar calculator is provided, whereby the gestational age of a fetus is calculated from the calendar date of the mother's last menstrual cycle. Using the calculated gestational age, the user of the calendar calculator may determine appropriate growth of fetal organs, determine the earliest time for detection of fetal anomalies, establish periods of risk to the fetus from drugs used by the mother, determine the appropriate times for testing for fetal anomalies, genetic abnormalities, or other fetal biochemical milestones. The calendar calculator of the present invention is designed for ease of use and for providing information previously unavailable to, or not conveniently accessible by, obstetricians and diagnostic technicians.

While the ultrasonogram is presently used as a primary diagnostic tool for prenatal testing, the calendar calculator may be used for other diagnostic tools, such as amniocentesis, chorionic villi sampling, and blood tests.

The fetomaternal calendar calculator is for multipurpose use throughout pregnancy.

Brief Drawing Description

Figure 1 is a top plan view of the fetomaternal calendar calculator of the present invention.

Figure 2 is a bottom plan view of the fetomaternal calendar calculator of Figure 1.

Figure 3 is an enlarged view of the fetal organ chart 32 of Figure 1.

Figure 4 is an enlarged view of the fetal anomaly chart 65 of Figure 2.

Figure 5 is a top view of the fetal organ chart 132 shown in a circular chart format.

Figure 6 is a top view of the fetal anomaly chart 165 shown in a circular chart format.

Detailed Description

One embodiment of the feto-maternal calendar calculator 10 comprises a flat rectangular card 14 having flat top and bottom surfaces 17, 20. The card 14 is formed of a suitable material on which printing or labels may be applied on top and bottom surfaces 17, 20 thereof.

The calendar calculator 10 also includes a gestation calculator 23. Gestational calendars, such as gestational calendar 23 are known in the art. Gestational calculator 23 includes a gestation period disk 26 rotatably connected at the center thereof to the top surface of card 14 by a hub 29. The disk 26 thereby overlays a portion of top surface 17, where top surface 17 allows space for a fetal organ chart 32, described hereinbelow. Disk 26 has an upper surface 35 on which are printed equally-spaced radial indicia 38 adjacent to the outer edge 41 of disk 26. Each indicia 38 represents a gestation period of one week. One of the indicia 38a is labelled "FIRST DAY OF LAST PERIOD", the 28th indicia from indicia 38a is labelled "VIABILITY" and the 40th indicia from indicia 38a is labelled "TERM". These labels each represent events which normally occur at the weeks of a pregnancy represented by the corresponding indicia.

Gestation calculator 23 further includes an annular calendar 44 printed on top surface 17 adjacent to and concentric with gestational period disk 26. It is also possible for annular calendar 44 to be printed on an outer disk (not shown) which is in turn fixed to top surface 17. In such an alternative arrangement, gestational period disk 26 would be concentric with the outer disk and rotatably connected at its center to the center of the outer disk. The gestational period disk 26 may also be rotatably connected to card 14 in a manner similar to that shown in Figure 1.

The annular calendar 44 is defined by an inner edge 47 concentric with outer edge 41 and adjacent thereto. The annular calendar 44 further includes equally spaced radial indicia 50 printed on top surface 17 adjacent to inner edge 47 where each indicia 50 represents a day of a calendar year as shown in Figure 1.

The gestation calculator 23 may be used to calculate, for a given calendar date, how

many weeks of the pregnancy have transpired by rotating gestation period disk 26 so that the indicia 38a labelled "FIRST DAY OF LAST PERIOD" points to the indicia 50 contained in annular calendar 44 representing the actual date of the first day the women's last period. After disk 26 is so positioned, the indicia 50 within annular calendar 44 representing the current date is identified. Indicia 50 within annular calendar 44 representing the current date will have pointing thereto an indicia 38 on disk 26 representing the number of weeks elapsed since the pregnancy began.

In one embodiment, fetal organ chart 32 is printed on top surface 17, preferably adjacent to gestation calculator 23, as shown in Figure 1. The fetal organ chart 32 may alternatively be printed on a label which is affixed to top surface 17. If the size of fetal organ chart 32 requires a substantial area of top surface 17, card 14 may be scored, grooved or otherwise dented to define creases about which card 14 may be folded when not in use to make the calendar calculator 10 more compact. Card 14 may have more than one such crease so that folding and unfolding the card resembles an accordion.

Fetal organ chart 32 includes an ordinate 53 along which are printed numerals 56 increasing in magnitude in the upward direction as viewed in Figure 1. Each numeral 56 represents the week into the pregnancy of a woman such that the greater the distance of a point on ordinate 53 from the bottom thereof, as viewed in Figure 1, the longer the duration of the pregnancy. Fetal organ chart 32 also has a series of columns 59 each containing a system grouping its related organs 62 of a fetus. The names of the organs 62 are printed at the elevation of ordinate 53, as viewed in Figure 1, representing the week into the pregnancy when the respective organ is expected to be first observable. The data regarding observability of the organs is determined from a statistically significant portion of the population via ultrasonography or other tests.

Fetal organ chart 32 may be used by locating the elevation along ordinate 53 corresponding to the current duration of a woman's pregnancy, hereinafter referred to as the organ reference elevation. The names of organs 62 contained in the various columns 59 which are positioned at the same or a lower elevation relative to the organ reference elevation will ordinarily be visible via a sonogram taken during the week into the pregnancy represented by the organ reference elevation.

Fetal anomaly chart 65 is shown in Figure 2 located on the bottom surface 20 of card 14. Fetal anomaly chart 65 may alternatively be printed on a label affixed to bottom surface

20. Fetal anomaly chart 65 includes an ordinate 68 along which are printed numerals 71 increasing in magnitude in the upward direction as viewed in Figure 2. Each numeral 71 represents the week into the pregnancy of a woman such that the greater the distance of a point on ordinate 68 from the bottom thereof, the longer the duration of the pregnancy. Fetal anomaly chart 65 has generally the same vertical orientation as fetal organ chart 32 such that the respective tops thereof are adjacent to the same edges of card 14. Fetal anomaly chart 65 also has a series of columns 74 each identifying an anatomical system, grouping its related anomalies 77 which may be present in a fetus. The names of the anomalies 77 are printed at the elevation of ordinate 68, as viewed in Figure 1, representing the week into the pregnancy of a woman when the respective anomaly may be first observable via a sonogram.

Fetal anomaly chart 65 may be used by locating the elevation along ordinate 68 corresponding to the current duration of a woman's pregnancy, hereinafter referred to as the anomaly reference elevation. The names of the anomalies 77 contained in the various columns 74 which are positioned at the same or a lower elevation relative to the anomaly reference elevation will ordinarily be visible via a sonogram taken during the week into the pregnancy represented by the anomaly reference elevation.

In use, gestation period disk 26 of the gestation calculator 23 is rotated as described above to determine the current week into a woman's pregnancy. Next, the elevation of the ordinate 53 of fetal organ chart 32 corresponding to the week calculated by gestation calculator 23 is identified in fetal organ chart 32, i.e., the organ reference elevation. Locating fetal organ chart 32 adjacent to the gestation calculator 23 results in ordinate 53 being adjacent to gestation calculator 23 thereby facilitating movement of the user's eyes from calculator 23 to chart 32. After identifying the organ reference elevation, the organs which are normally visible via a sonogram at the calculated duration of the pregnancy may be determined. The card 14 may then be flipped over to view fetal anomaly chart 65 on bottom surface 20. The elevation of ordinate 68 of fetal anomaly chart 65 corresponding to the week calculated by gestation calculator 23 is identified in the fetal anomaly chart, i.e., the anomaly reference elevation. After identifying the anomaly reference elevation, the anomalies which are normally visible via a sonogram at the calculated moment of the pregnancy may be determined. Identification of organs and anomalies in a sonogram during the taking of the sonogram, i.e., in "real time" is thereby facilitated.

The calendar calculator 10 may also include an elongate guide structure (not shown),

such as a straightedge or ruler, having at least one flat surface for overlaying the regions of top and bottom surfaces 17, 20 containing fetal organ and anomaly charts 32, 65. The guide structures overlay respective charts 32, 65 in generally perpendicular orientations relative to respective ordinates 53, 68. The guide structures are movable relative to top and bottom surfaces 17, 20 in at least the direction parallel to respective ordinates 53, 68. An example of connecting the guide structure to card 14 enabling such movement is one or more pins (not shown) extending from the guide structure into corresponding slots (not shown) formed in card 14 where the slots are parallel to respective ordinates 53, 68. Other configurations for connecting the guide to card 14 are possible.

In use such guide structure is positioned so the lower edge thereof coincides with the reference elevation along respective ordinates 53, 68 corresponding to the week calculated by gestation calculator 23. The guide structure is thereby positioned above the fetal organs and/or anomalies 62, 77 which are normally visible via a sonogram after the number of weeks calculated by the gestation calculator 23. Identification of the portions of fetal organ and anomaly charts 32, 65 below the reference elevation, corresponding to the week calculated by gestation calculator 23, is thereby possible without referring back to the numerals 56, 71 adjacent to ordinates 53, 68 which may in turn require remembering the week calculated by gestation calculator 23 or referring back thereto. Efficiency and ease of examining fetal organ and anomaly charts 32, 65 may thereby be improved. The portions of charts 32, 65 below the reference elevation, corresponding to the week calculated by gestation calculator 23, is typically of interest to the examining physician since these portions of charts 32, 65 contain organs and anomalies 62, 77 which if present are normally visible via a sonogram. The guide structure may be opaque, have windows or be completely transparent.

The guide structures may be movable by applying a force directly thereto, e.g., by hand, in the desired direction of movement of the guide structure. The force may be applied through a mechanical linkage with gestation period disk 26 such that rotation of disk 26 will produce concomitant movement of the guide structure. Such a linkage may be calibrated to automatically position either or both guide structures so that the lower edges thereof coincide with the week into the pregnancy calculated by gestation calculator 23.

An alternative embodiment of the calendar calculator 10 includes a radial window (not shown) formed in gestation period disk 26 and information on fetal development printed on

portions of top surface 17 overlain by disk 26. This information on fetal development is positioned on gestation period disk 26 such that when disk 26 is rotatably positioned to calculate the current week into a woman's pregnancy, fetal information corresponding to the calculated week into the pregnancy is displayed through the window of disk 26. When the information obtainable thereby displayed contains the data of fetal organ and anomaly charts 32, 65, the content of charts 32, 65 thereof may be reduced, or, possibly, one or both charts 32, 65 eliminated entirely. Reductions in the content of charts 32, 65 may reduce the required size of card 14 allowing card 14 to be circular and concentric with gestation period disk 26.

In a still further alternative embodiment, calendar calculator 10 may include charts and/or nomograms of other feto/maternal tests other than the ultrasonography described above in connection with fetal organ and anomaly charts 32, 65.

In another embodiment, the calendar calculator 10 may include circular charts, such as those shown in Figures 5 and 6 as fetal organ and anomaly charts 132, 165. These charts may operate in conjunction with or independent from the gestational period disk 26. Fetal organ chart 132 includes circles 153 upon which are printed numerals 156, representing weeks of the pregnancy, where the value of numerals 156 increases in magnitude in a direction along a radius of the circle formed by the chart 132. Fetal organ chart 132 also has a series of wedges 159 each containing a system grouping related organs of a fetus. The names of the organs are printed at the radial distance of circles 153, representing the week into the pregnancy when the respective organ is expected to be first observable.

Fetal anomaly chart 165 includes circles 168 upon which are printed numerals 171, representing weeks of the pregnancy, where the value of numerals 171 increases in magnitude in a direction along a radius of the circle formed by the chart. Fetal anomaly chart 165 has generally the same orientation as fetal organ chart 132 such that the charts may be overlaid. Fetal anomaly chart 165 also has a series of wedges 174 each identifying an anatomical system, grouping related anomalies which may be present in a fetus. The names of the anomalies are printed at the radial distance of circles 168, representing the week into the pregnancy of a woman when the respective anomaly may be first observable.

As an additional feature, movable guides (not shown) may be affixed to the circular charts, where such guides selectively reveal and cover organ names 162 or anomaly names 177, allowing the user of the invention to focus easily on the relevant data. One embodiment

of the guide would be rotatably affixed at the center of the circular charts.

The calendar calculator 10 may have a plurality of rotatable disks 26 rotatably connected to card 14, or to each other, where each rotatable disk provides fetal-maternal information as described above. Card 14, with one or more disks 26 attached, may be creased
5 between the disks so that card 14 may be folded in the manner of an accordion to a closed position where the disks become sandwiched between sections of card 14. Alternatively, more than one such rotatable disk may be attached to separated sections of card 14 where the ends of the cards are rotatably connected as at tab 180 such that the cards open in the manner of a fan.

10 In another embodiment, the calendar calculator may be implemented in software, where such software may operate independent from, or in conjunction with, diagnostic aids.

It will be appreciated that the above is merely illustrative of a few embodiments, and that modifications of detail or assembly such as inner and outer charts/discs rotatably connected or back to back operated, or disclosing windows of fetal-maternal information, or ruler format or any other formats, can be made without departing from the scope and
15 principles of the invention.

While certain novel features of this invention have been shown and described, it will be understood that various omissions, substitutions and changes in the forms and details of the device illustrated and in its operation can be made by those skilled in the art without
20 departing from the spirit of the invention.

CLAIMS

1. A feto-maternal calendar calculator comprising:
a gestational age calculator for calculating a fetal gestational age;
a first data set comprising at least one of fetal organ appearance data, fetal anomaly
appearance data, maternal drug intake interaction data, genetic abnormality data, and
fetal biochemical data, said data set being indexed by gestational age; and
means for viewing a subset of the first data set, which subset comprises a range of
preselected gestational ages, where the calculated fetal gestational age falls between
the preselected gestational ages.
2. The calendar calculator of claim 1 wherein the first data set is further indexed by at
least one of fetal organ systems and fetal maternal compartments.
3. The calendar calculator of claim 1 further comprising means for correlating the fetal
gestational age with the first data set to produce a second, time-oriented data set, where such
second data set is a subset of the first data set.
4. The calendar calculator of claim 1 wherein the subset of the data set is limited to a
class of information selected from at least one of a fetal organ system and a fetal maternal
compartment.
5. The calendar calculator of claim 1 wherein said gestational age calculator is an analog
calculator, and said fetal organ data and said fetal anomaly data are charts correlating
gestational age with fetal organ appearance and fetal anomaly appearance respectively.
6. The calendar calculator of claim 5 wherein
each of said charts is printed on or affixed to a first substrate;
said gestational age calculator is printed on or affixed to a second substrate having
movable portions permitting alignment of a first day of a pregnant female's last
menstrual period with an actual calendar date on which said first day occurred and
showing thereby a gestational age of a fetus on any calendar date of interest; and
said gestational age calculator being affixed to a surface of said first substrate.

7. The calendar calculator of claim 1 wherein said gestational age calculator is a circular gestational age calculator affixed to a substrate; and said data set is displayed on a circular chart.

8. The calendar calculator of claim 7 further comprising a plurality of data sets displayed on circular charts, wherein each of said gestational age calculator and said circular charts is affixed to different portions of a single substrate, which substrate is capable of being folded with said gestational age calculator and said circular charts attached so that the calendar calculator may be carried in a pocket.

9. The calendar calculator of claim 7 wherein each of said gestational age calculator and said circular charts further comprise a tab on at least one portion of the circumference thereof, and each of said gestational age calculator and said circular charts are movably connected to at least one of the others at a point on said tabs, such that when moved into a closed position the gestational calculator and said circular charts have a compact appearance.

10. The calendar calculator of claim 9 wherein, when fully opened, the gestational calculator and said circular charts are capable of being viewed simultaneously, giving the appearance of disks in a fan shape or as a chain of disks or a combination thereof.

11. A method of determining appropriate diagnostic tests to perform on a pregnant female and on a developing fetus comprising:

obtaining a calendar date on which said pregnant female had a first day of her last menstrual period before becoming pregnant;

entering said calendar date into a feto-maternal calendar calculator;

obtaining an output of a gestational age of said fetus on a given date and at least one of

fetal organs detectable by a diagnostic technique on or about a given date;

fetal abnormalities detectable by a diagnostic technique on or about a given date, if such abnormality were then present;

maternal drug intake interactions with the fetus on or about a given date;
genetic abnormalities detectable by a diagnostic technique on or about a given
date, if such abnormality were then present; and
fetal biochemical data detectable by a diagnostic technique on or about a given
date.

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12. The method of claim 11, wherein the given date is the calendar date.

13. A feto-maternal calendar calculator comprising
a circular substrate having two sides;
a gestational calculator affixed to one side of the circular substrate; and
a circular chart on the opposite side of the circular substrate, where the circular chart
comprises a data set comprising at least one of fetal organ appearance data, fetal
anomaly appearance data, maternal drug intake interaction data, genetic abnormality
data, and fetal biochemical data, said data set being indexed by gestational age.

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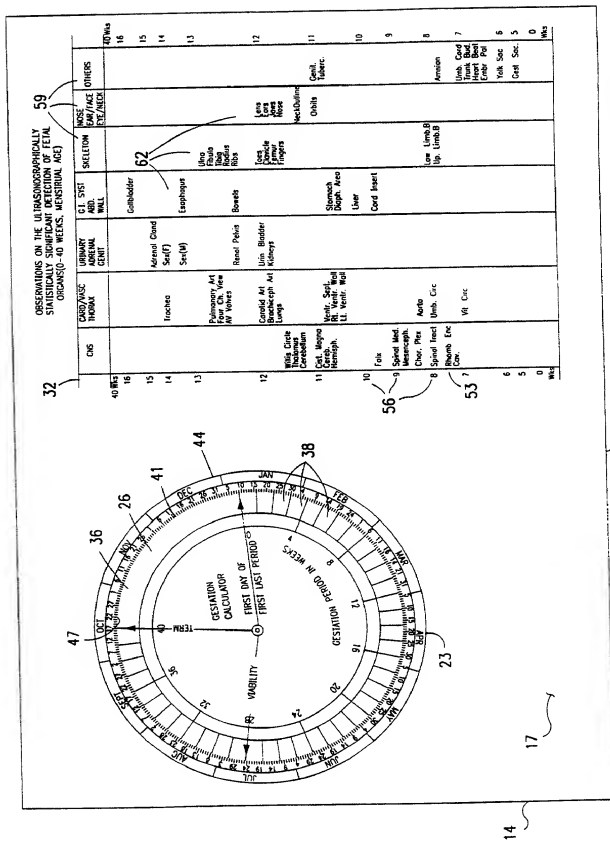


FIG. 2

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OBSERVATIONS ON THE ULTRASONOGRAPHICALLY
STATISTICALLY SIGNIFICANT DETECTION OF FETAL
ORGANS(0-40 WEEKS, MENSTRUAL AGE)

	CNS	CARD/VASC THORAX	URINARY ADRENAL GENIT	G.I. SYST ABD. WALL	SKELETON	NOSE EAR/FACE EYE/NECK	OTHERS	
40 Wks								40 Wks
16				Gallbladder				16
15			Adrenal Gland					15
14		Trachea	Sex(F)					14
13			Sex(M)	Esophagus				13
		Pulmonary Art. Four Ch. View AV Valves	Renal Pelvis	Bowels	Ulna Fibula Tibia Radius Ribs			
12		Carotid Art. Brachioceph Art. Lungs	Urin. Bladder Kidneys		Toes Clavicle Femur Fingers	Lens Ears Jaws Nose NeckOutline		12
11	Willis Circle Thalamus Cerebellum					Orbits	Genit. Tuberc.	11
	Cist. Magna Cereb Hemisph.	Ventr. Sept. Rt. Ventr. Wall Lt. Ventr. Wall		Stomach Diaph. Area				
10				Liver				10
9	Falx			Cord Insert.				9
8	Spinal Med. Mesenceph. Char. Plex	Aorta						8
	Spinal Tract	Umb. Circ.			Low Limb.B Up. Limb.B		Amnion	
7	Rhomb. Enc. Cov.	Vit. Circ.					Umb. Cord Trunk Bud. Heart Beat Embr. Pol.	7
6							Yolk Sac	6
5							Gest. Sac.	5
0								0
Wks								Wks

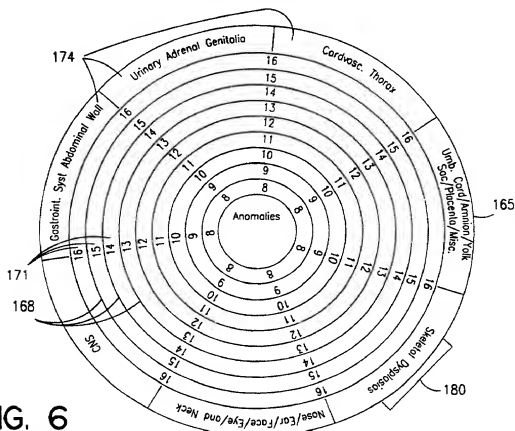
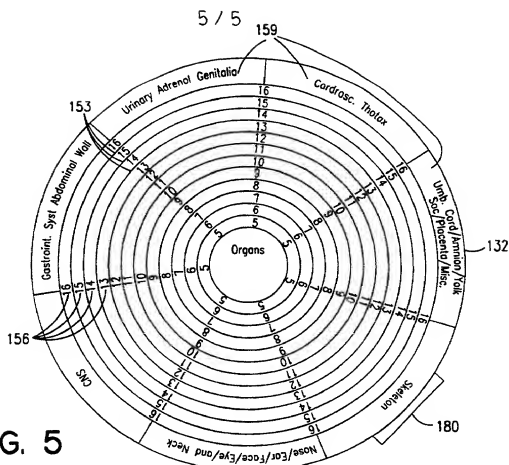
FIG. 3

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OBSERVATIONS ON THE ULTRASONOGRAPHICALLY DETECTABLE ONSET OF FETAL ANOMALIES ORGANS(0-40 WEEKS, MENSTRUALAGE)

	CNS	CARD/VASC THORAX	URINARY/ ADRENAL/ GENITALIA	GASTROINT. SYSTEM/ ABDOMINAL WALL	SKELLETAL DYSPLASIAS	NOSE EAR/TACEL EYE/NECK	UMB. CORD/ AMNION/ YOLK SAC/ PLACENTA/ MISC.
40 Wks							
68		Pulmonary Hematoma Agenesis of Veno Cava Aortic Stenosis Endocardial Fibroelast Tos/ Corrected TGA Double Out Rt. Ve Coarctation of Aorta Urinal Agenesis	Absent Genitalia Atrial Septal Defect Double Collect Syst	Gallbladder Dysmorphism Gallbladder Agenesis Pancreatic Cyst Solid Liver Tumor Double Gallbladder	Facemelo Acroly Tarsus Eumelanus Arthropogonist Rockerbottom Foot Clubhand		
Hydrocephalus LV		Hypoplastic Lt Heart					
15		Ventric. Septal Def	UPJ Obstruction		Osteogen Imperf2	Cleft Lip and Palate	
Hemol. of Mening		Hypot. Ascend. Aorta Coronary Atery	Epispadias		Larsen Syndrome		
Char. Pt Dysmorphism			Hypoplasia Monost. Renal Agenesis	Mesenteric Cyst Reptomelagly	Caudal Regr. Synd Sirenomelia	Cranial Hemangioma Microphthalmia	Amn. Band Syndr Plac. Hypertrophy Velomelanosis Insert
14		Aortic Hydronephrosis Septal Cysticulations Calcifications		Duodenum Hernia/Stom	Amelia (inferior) Amelia (superior) Camptodacty Hemivertebra Clenched Fingers	Cathartact	Single Umbil Artery
Spina Bifida/Closed			Prune Belly Synd Bilateral Renal Agenesis	Esophageal Bowel Omphalocele/BALB Heart Intestine. Cholec. Cyst		Anophthalmia Arhinia	
13						Medial Cleft Lip	
Neurohydrocephalus		Stress Inertus Teratoma of Fetus	NOCK		Theracophagus Hydrophosphatosis Scoliosis	Low Set Ears	Skin Tumor Arteriovenous Scars Cap Terat
71			Hydronephrosis Dysl Kidney	Omphalocele/Bowel		Macroglossia	TRAP Mult. Pteryg. Synd.
Diast. CSF/ Central Encephalocele					Achondro II Clubfoot	Probasia Cyclops	
12		Agenesis of Aorta (12) Esophageal (12) Truncus Art. (12+ve) Peric Myo Urt. Dis (12)	Pelvic Kidney	Folding Defect Urethral Cyst Liver Calcifications Omphalocele/BALB Esoph. Air	Diast. Dwarf		
Hydrocephalus 3v			Horseshoe Kidney				
Ancephaly		Single Ventricule					
Spina Bifida/Open Menigoencephalocele		A-V Canal Common Atrium Complete Heart Block A-V Valve Regurgital					
71							
Dandy-Walker Malfo			Post Urethral Valve	Gastroscisis	Omphalocephalocephog		
Encephalocele/Occip			Renal Cyst		Polydactyly		
11		Epistaxis Anomaly Dextrocardia Pericardial Cyst	Hydrocephalus		Jarcho Levine Syndr. Syndactyly	Hypotelism	Partial Mole
10							Plac. Cyst
Hydrocephalus/Semilob							
Hydrocephalus							
9		Thoracic Hydronephrosis Pericardial Effusion					
Intestinal Tumor							
Choroid Plexus Cyst							
8							
7							
0							
Wks							

FIG. 4



Docket No.
43581.010100

Declaration and Power of Attorney For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

Feto-Maternal Calendar Calculator

the specification of which

(check one)

- ☐ is attached hereto.
- ☒ was filed on 6 March 1997 as United States Application No. or PCT International Application Number PCT/US97/04127 and was amended on _____ (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

(Number)

(Country)

(Day/Month/Year Filed)

☐

(Number)

(Country)

(Day/Month/Year Filed)

☐

(Number)

(Country)

(Day/Month/Year Filed)

☐

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, C. F. R., Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(list name and registration number)*

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